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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,350	10/11/2001	Martin J. Jacobs	CP215	9510

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,350	Applicant(s) JACOBS ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-15, 17-20 and 32-54* is/are rejected.

7)☒ Claim(s) *12,16 and 21-31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 & 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of, response to notice to file missing parts of application and request for corrected filling receipt filed 02/01/02, information disclosure statement filed 03,01,02, corrected filling receipt filed 05/31/02 and supplemental information disclosure statement filed 06/11/02.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites "non-aqueous" composition while the rest of the claims are directed to aqueous composition. It is unclear how the Modafinil composition permits both aqueous (in most of the claims) and non-aqueous environments (in one claim).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6, 32, 33, 36, 37, 39, 41-44, 47, 48, 51,52, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Grebow et al. (US 5,618,845).

Grebow teaches a pharmaceutical composition comprising modafinil particles or modafinil pharmaceutically acceptable salt particles (abstract, column 2, column 3, lines 1-55 and claims 1 and 2) and non-toxic pharmaceutically acceptable carrier (column 4, lines 4-10). Grebow's composition contains an appropriate dosage of between 50 mg and 700 mg of modafinil with a preferred amount of 400 mg (column 4, lines 11-18 and column 10, lines 15-17). The modafinil pharmaceutical composition is administered as a tablet, capsule, powder, pill, liquid, suspension or emulsion; the modafinil composition can also be administered topically via epidermal patch or administered via direct injection (column 10, lines 18-26). Grebow further teaches a method of altering somnolent state, for example, narcolepsy, idiopathic hypersomnia and related sleep disorders by administering to a mammal a pharmaceutical composition comprising an effective amount of modafinil particles; and an effective amount of the pharmaceutical composition is defined as an amount effective for treating the somnolent state (column 3, lines 56-67). In human clinical trials, modafinil is administered to physically and mentally healthy male subjects (column 5, lines 46 to 56).

The composition of Grebow encompasses stable and unstable suspensions because the prior art does not exclude stable suspensions and thus the suspension of Grebow would be inherently stable. Grebow clearly teaches the composition and methods of the application recited in the claims designated above. Therefore, the teachings of Grebow meet the limitations of the claims.

5. Claims 1-4, 6, 7, 11, 14, 15, 32, 33, 36, 37, 39, 47, 51 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Nguyen et al. (US 5,843,347).

Nguyen teaches a pharmaceutical composition comprising particles or microparticles of active ingredient, physiologically acceptable hydrophilic excipient and water (abstract). The hydrophilic excipient comprises a polymer component and a water-soluble or water dispersible component that acts as a diluent (column 6, lines 1-5). The polymer component is selected from the group consisting of gum Arabic, xanthan gum, gum tragacanth, alginates, pectinates, polyvinylpyrrolidone, **polyethylene glycols**, cellulose, carboxymethyl cellulose, cellulose ethers, carboxymethyl chitin, dextran, chitosan, gelatin, acrylic and methacrylic polymers and copolymers, colloidal silica and mixtures thereof (column 6, lines 11-23). The water-soluble or water dispersible component is selected from the group consisting of lactose, glycocoll, mannitol, glucose, sucrose, maltodextrin, cyclodextrins and derivatives thereof (column 6, lines 44-49). The hydrophilic excipients can also comprise surfactants that are capable of oral administration and the surfactants can be polysorbates, sorbitan esters, fatty glyceride polyethers, lecithins, sodium lauryl sulfate, sodium dioctylsulfosuccinate and mixtures thereof (column 7, lines 2-7). The process of preparing the modafinil particles involves homogenization of the active ingredient in solution, suspension, or emulsion and freeze drying or lyophilization (column 8, lines 15-24). The active ingredient is selected form the group consisting of paracetamol, probucol, piroxicam, phloroglucinol, tiadenol, flerobuterol, **modafinil**, dexfenfluramine, carbinoxamine maleate, loperamide, lorazepam and mixtures thereof (claim 13). Oral administration is route of administration and route of administration of a composition is not critical in a composition claim.

Nguyen does not exclude stable emulsion and since the prior art is silent on whether the emulsion is stable or unstable, the emulsion of the prior art would necessarily be stable since

Nguyen does not teach that the emulsion is unstable and since the emulsion is homogenized and lyophilized. Nguyen does not specifically refer to polyethylene glycol as an organic solvent; but since one of the organic solvents in the application is polyethylene glycol, Nguyen teaches polyethylene glycol organic solvent. The method steps in claims 36 and 37 broadly contacts modafinil particles with water and the composition of Nguyen contains water. Thus Nguyen clearly teaches the composition and the methods of the application in the claims designated above. Therefore, the teachings of Nguyen meet the limitations of the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 17, 18, 34, 35, 38, 45, 46, 49, 50 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845).

The teachings of Grebow are as described above where it is noted that the appropriate dosage of modafinil is between 50 mg and 700 mg with a preferred amount of 400 mg (column 4, lines 11-18 and column 10, lines 15-17). The dose or amount of modafinil in the composition of the application recited in claims 17, 18, 34 and 35 is encompassed in the amounts disclosed by Grebow. Grebow also teaches administering the prior art composition in clinical trials to mentally and physically healthy male subjects. Orally administering modafinil particles to human subjects (column 5, lines 46-56) would necessarily bring modafinil particles in contact with the aqueous environment in the human subject since human body is mostly water.

Claim 3 of the application does not recite any dose and claims 45 and 46 depend from claim 3. But the dose/amount of modafinil administered to a subject in need thereof in the prior art is effective for treating the somnolent state, and thus modafinil would be present and capable of detection in the blood serum of said subject because, for a drug to be effective, it has to be present in the blood circulation. In the absence of a showing to the contrary, modafinil blood serum levels of 0.05 to 30 μg/ml do not patentably distinguish the invention over the prior art.

Thus, Grebow clearly teaches the composition and methods of the application except that the prior art is silent on the form of the capsule. Since the prior art is silent on the form of the capsule, hard or soft gelatin capsule, the prior art's broad teaching of a capsule encompasses both soft gelatin capsule or hard capsule. The expected result would be a modafinil particle composition encapsulated in soft gelatin capsule or hard capsule. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to encapsulate the modafinil particle composition in hard capsule or soft gelatin capsule because the prior art broadly teaches capsules and capsules can either be soft or hard. One having ordinary skill in the art would have been motivated to encapsulate the composition of the prior art in soft gelatin capsules or hard capsules since the prior art does not exclude either form of the capsule.

8. Claims 8-10, 13, 17-20, 34, 35, 38 and 40-46 rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Lafon (US 5,180,745).

Nguyen is discussed above. However, Nguyen fails to teach administering the composition to a subject in need thereof to treat any of the conditions recited in claim 44.

But, Lafon teaches a method of treating Parkinson's disease where the method comprises administering to a patient in need thereof a therapeutically effective amount of modafinil (claim

1) . For modafinil to be effective in treating Parkinson's disease, the modafinil administered must be carried by the blood to the target areas, which implies that the level of modafinil in the blood serum is effective for treating the Parkinson's disease. In the absence of a showing to the contrary, modafinil blood serum levels of 0.05 to 30 μg/ml do not patentably distinguish the invention over the prior art.

Parkinson's disease is one of the conditions recited in claim 44. Lafon teaches that the dose administered to humans varies form 50 mg to 1000 mg (column 1, lines 33 and 34). The dose of 200 mg and 100 mg recited in claims 34 and 35 lie within the disclosed range of 50-1000 mg.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to orally administer the composition of Nguyen to treat Parkinson's disease because Lafon administers modafinil to treat the disease. One having ordinary skill in the art would have been motivated to treat Parkinson's disease by administering to a subject in need of treatment the composition of Nguyen where the modafinil dose is 50 mg to 1000mg because Lafon teaches that the dose of modafinil administered to humans varies from 50 mg to 1000 mg.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 3-5, 14, 15, 32-34 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 8, 10-13 and 26-29 of co-pending Application No. 09/974,473. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application recites in claims 1 and 3-5 a pharmaceutical composition where the composition is non-aqueous and particulate and comprises modafinil compound that is modafinil. The co-pending application teaches in claims 1-3 a non-aqueous pharmaceutical composition that comprises a modafinil compound that is modafinil. The difference between the application and the co-pending application is that the application is directed to a particulate form of modafinil and the co-pending is silent on particulate form of the drug. However the generic teaching of modafinil in the co-pending application encompasses modafinil particles of the examined application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 12, 16 and 21-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
August 10, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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